EVALUATION OF IRRADIATED FOODS AND OTHER ITEMS WITH TELEMETRIC DOSIMETERS AND ASSOCIATED METHODS

Related Applications

This application claims the benefit of priority from U.S. Provisional Patent Application Serial Number 60/222,502, filed August 2, 2000; the contents of this application are hereby incorporated by reference as if recited in full herein.

Field of the Invention

The present invention generally relates to the assessment or quantitative evaluation of the amount of radiation delivered to an object undergoing sterilization *in situ*.

Background of the Invention

Providing a food supply that is safe for consumption can be problematic, particularly because suitable control measures can be hard to enforce as the producers, distribution chains, and markets become more global. In addition, visual inspections are not always reliable as a means of detecting harmful contaminants. Further, cross contamination of foods can occur during handling (including during harvesting, shipping, and packaging), that can infect food typically believed to be relatively safe from pathogens. For example, *E. coli* bacteria, which is typically found in certain meats, can also be found in "fresh" vegetables and fruits. The presence of atypical bacteria in foods can be attributed to the use of particular types of fertilizers or to processing conditions. Certain processing conditions may allow direct contact of various food items with contaminated products, while others may allow for indirect contamination such as via contact with contaminated containers or work surfaces, each of which can allow the undesirable spreading of contaminants.

Certain safety precautions can be taken to reduce the risk of illness associated with the consumption of foods which may carry pathogens, such as washing the fruit and vegetables before consumption and/or cooking meat or other food items to or above a certain temperature. While washing vegetables and fruits can dilute or remove the contaminant(s) from the food, and cooking the food to a temperature sufficient to kill the bacteria may reduce the exposure risk, not all foodstuffs are washed or properly cooked before they are eaten. Further, children can be especially vulnerable to harmful exposures, as many do not reliably pursue these safety measures and exposure to relatively small amounts of harmful contaminants can be more profound relative to healthy adults. A consumer has little control over what safety steps (*i.e.*, washing and/or cooking food properly), are followed by personnel at a food service outlet.

Processing foods to reduce or even eliminate unwanted microorganisms can be an important step forward in the reduction and elimination of the risk of illness due to exposures to contaminated foods. One economic and effective way to rid food of contaminating microorganisms is to irradiate food with ionizing radiation to effectively "sterilize" the food to destroy the harmful microorganisms therein (irradiation can be used to sterilize other objects such as medical devices). This can be an effective and economic tool in improving the safety of the food supply to thereby provide safe, sterilized food items which have reduced (and potentially even undetectable) levels of harmful microorganisms.

Generally stated, there are two primary modalities used to irradiate food and other items to achieve sterilization. One modality includes the use of a radioactive element such as Cobalt-60, and the other employs electron beams produced by a linear accelerator. The radiation dose should be monitored to ensue that pathogens are destroyed effectively. For food or edible items, radiation doses in the 0.15 kGy to 10 kGy range are typically used, while for devices and objects, radiation doses are higher, typically up to 20 kGy or more.

Conventionally, in order to monitor the radiation doses provided by the irradiation process, either TLD's (thermoluminescent devices) or chromatic tags are used. TLD's can be generally described as crystals, *e.g.*, lithium fluoride, the structure of which is changed (damaged) during exposure to radiation. More

particularly, during irradiation, electrons travel to and are trapped in the crystal after being ejected by the high-energy (ionizing) photons used for sterilization. Upon exposure to heat, the electrons in the crystal fall back to their ground states and emit light as result of the change. A spectrophotometer is used to measure this light and provide a quantitative assessment of the amount of radiation to which the device was exposed. A technician typically recovers the TLD from an irradiated package and then analyzes/measures the emitted light on the spectrophotometer. Unfortunately, this process can be relatively labor-intensive and can be undesirable for use in a mass production environment.

Chromatic tags can be described as plastic tags (formed of materials such as PMMA) which undergo a color change upon exposure to radiation at some level. However, generally stated, the color change is often a subjective evaluation when done visually by an inspector. To receive a more reliable assessment, colormetric readers are used to quantify the color change to a more exact level. This can be compared to the use of radiographic film wherein the level of exposure on the film corresponds to the intensity of the dose received. Unfortunately, again, the determination of the dose measured in this manner can also be labor intensive and/or unsuitable for a mass-production environment.

Objects and Summary of the Invention

It is therefore an object of the present invention to provide a cost-effective dosimeter, which can be used to evaluate the radiation dose delivered to an item undergoing sterilization.

It is yet another object of the present invention to provide improved methods to evaluate a radiation dose(s) delivered to a plurality of sterilized packaged food items without requiring direct human intervention.

It is a further object of the present invention to provide economic methods and devices which are suitable for mass-production environments and which can automatically relay and/or correlate production and/or process information to an irradiation dose.

It is an additional object of the present invention to provide an economic automated method of determining the amount of radiation delivered to an item *in situ*.

It is another object of the present invention to provide an economic dosimeter configuration, the sensing element of which can be embedded in a packaged and/or sealed food or medical item.

These and other objects can be satisfied by the present invention by a radiation dosimeter which is adapted to change the value of an associated electronic parameter in a detectable manner dependent upon the amount of radiation it is exposed to. The value of the electronic parameter can be relayed automatically (or semi-automatically) and used to determine and provide the radiation dose for a sterilized item, preferably a food or edible item, without requiring human intervention. The sensor can be configured as a single use, disposable, passively operated wireless or telemetrically operated sensor.

More particularly, a first aspect of the invention is a method for determining the irradiation dose delivered to an object. The method includes the steps of (a) irradiating at least one object with a radiation dose which is sufficient to sterilize the object; (b) positioning a sensor on the object such that it is held proximate the object during the irradiating step, the sensor has associated operational parameters, and one or more of the operational parameters is configured to change responsive to the irradiating step; (c) transmitting data associated with the operational change in the parameter of the sensor; and (d) determining the radiation exposure dose based on the data provided by the transmitting step. In certain embodiments, the transmitting step can be performed such that is carried out by a wireless or telemetric transmission.

A second aspect of the present invention is a radiation dose evaluation system. The system includes a radiation source and at least one dosimeter sensor adapted to be positioned on an object undergoing irradiation treatment such that the sensor is exposed to an amount of radiation representative of the amount of radiation exposure introduced to the object. The system also includes a wireless or telemetric reader operably associated with the sensor such that it receives data associated with the sensor and a controller operably associated with the reader. The system also includes a computer program operably associated with the controller. The computer program can be configured to analyze data transmitted from the sensor to the reader or receiver to determine a radiation dose associated therewith.

In certain embodiments, the system is configured to evaluate radiation levels above about 0.1kGy, and typically for food or edible items, in a range of from about 0.15-10kGy (with pet and animal foods, spices, melon, herbs and seasonings approved up to about 30kGy), but more typically about 1-7kGy, and for other sterilized items such as medical implements and devices in a range of from about 10-50kGy.

Another aspect of the present invention is a passively operated (it does not require a power source such as its own battery) radiation dose sensor. The sensor includes a "tank" circuit which, in operation, is configured to provide an electrical output that changes in a predictable (dose-correlated) manner when exposed to radiation in the desired irradiation dose range (for many food items above about 0.1kGy, and more preferably in the 0.1-10kGy range). The sensor tank circuit includes a capacitor and an inductor operably associated with the capacitor. In operation, the sensor is passively configured to be inductively powered by a remote reader/receiver (without requiring a battery or voltage regular or discrete power source on the sensor itself). Thus, the sensor is configured such that it alters at least one electrical property responsive to the amount of exposure to radiation which is then used to determine the amount of radiation the sensor receives (and/or is exposed to).

In certain embodiments, the sensor is passively configured to provide a reflected signal output and has an electronic circuit comprising a MOS device such as a MOS capacitor or FET structure semiconductor device configured to withstand and provide a wireless or telemetrically detectable radiation sensitive output responsive to particular levels of irradiation exposure (for most food items, the operational range is in about the 0.1-10kGy range, *see* **Figure 1B**). In other embodiments, the electronic circuit comprises other components and parameters to evaluate radiation dose, such as the Hfe or β of a bipolar transistor or the leakage current of a diode or the coupling factor (K) between primary and secondary circuits.

In certain embodiments, the sensor circuit semiconductor or MOS device is a RADFET which is sensitive in the irradiation dose range being monitored (*i.e.*, it has a suitable rad-hardness corresponding to the food item undergoing electronic sterilization). The RADFET is operably associated with a flat form coil (typically

secured or bonded to a copper or foil or mylar coil). The sensor circuit has a pre-irradiation exposure threshold voltage value and a threshold voltage which varies corresponding to the irradiation level to which it is exposed. The threshold voltage can be used to determine the radiation dose delivered to the sensor (and with the sensor on or in proximity to the product, to the product itself).

The detection system can be configured to detect other electronic outputs or parameters. For example, the sensor tank circuit can have a detectable first resonant frequency prior to exposure to radiation above a threshold level, and a plurality of altered or changed resonant frequencies different from the first resonant frequency corresponding to the amount of radiation exposure it experiences above the threshold level. Alternatively, or in addition to, the sensor electronic circuit can be configured such that it alters its Q factor based on exposure to radiation and, as such, the Q factor values can then correlated to the radiation exposure level to determine the associated radiation dose.

In an alternative embodiment, the sensor tank circuit can be configured with a capacitor having a central dielectric formed of a material which changes one or more of its conductivity, capacitance value, or dielectric constant responsive to radiation exposure level.

As noted above, for edible items, the sensor is preferably configured to detect radiation doses in the range of from about 0.1-10kGy, and more preferably about 0.5-10 kGy and for other items such as medical devices, the sensor is preferably configured to detect radiation doses in the range of from about 10-50 kGy. Of course, application specific sensors or sensors which operate in more narrow ranges within the overall range of interest (suitable for more than one product type) can also be provided to allow for a more narrow radiation sensitive sensor (*i.e.*, one for beef and/or poultry, one for pet food, one for fruit, one for grains, etc., or a 0.1-0.5kGy, a 0.5-2kGy, a 2-4kGy, a 1-4 kGy, a 2-5 kGy, and the like).

The sensor may also be configured with a low profile when viewed from the side to allow for easier processing and a reduced likelihood of handling damage which may occur in a mass production environment. Indeed, the sensor may be integrated into a package configured to hold the object undergoing irradiation. The package may be sealed with the sensor thereon or therein prior to irradiation.

Another aspect of the invention is a method for determining the radiation dose of a product. The method includes the steps of (a) positioning a sensor with a tank circuit on an object; and (b) irradiating the object and the sensor to a level which is sufficient to sterilize the object and to induce alteration in a predetermined operational parameter of the sensor, the degree of alteration representative of the amount of irradiation received by the sensor. The data may be wirelessly transmitted from the sensor to a receiver.

In certain embodiments, the object is sealed within a container prior to irradiation so as to reduce the likelihood of exposure to airborne or other contaminants after the sterilization process.

The present invention provides cost-effective irradiation dosimeter systems and dosimeter sensors that can be employed in a mass production environment. The systems and sensors can be used to quantify or evaluate radiation exposure or doses for items which have been electronically pasteurized to prepare and process uncooked and frozen commercial sized and/or bulk food items for safer consumption. The system can also be used to monitor irradiation delivered to inhibit the decay of food items conventionally introduced by microorganisms living therein, thereby reducing the amount of food which conventionally has been unable to be sold due to undesirable decay and/or spoilage. The system reduces inspection labor requirements (eliminating the requirement of visual inspection or physical intervention to determine the dose) and can improve the reliability of the production process itself by providing radiation dose information on a substantially real-time basis to allow faster adjustment of process parameters. The system can be used in cold environments (where food is refrigerated or frozen), ambient, and hot (where food is cooked) environments.

The foregoing and other objects and aspects of the present invention are explained in detail in the specification set forth below.

Brief Description of the Drawings

Figure 1A is a schematic illustration of a radiation measurement system according to the present invention.

Figure 1B is a table listing foods approved by the US Food and Drug Administration ("FDA") for irradiation in the United States and their corresponding maximum doses.

Figure 2 is a flow chart of operations that can be used to assess radiation doses according to embodiments of the present invention.

Figure 3 is a flow chart of a method used to control the radiation dose according to embodiments of the present invention.

Figure 4 is a schematic diagram of an irradiation monitoring system according to the present invention.

Figure 5A is a schematic diagram of a dosimeter sensor circuit according to one embodiment of the present invention.

Figure 5B is a schematic diagram of the circuit shown in **Figure 5A** illustrating the operation of the MOS device with a voltage source used to model the radiation effect.

Figures 5C and **5D** are graphs of a response signal, **Figure 5A** illustrating the signal below the threshold voltage and **Figure 5B** illustrating the waveform affected by the activation of the device (at values above the threshold voltage).

Figures 5E and **5F** are schematic diagrams of alternate embodiments of a dosimeter sensor circuit according to the present invention.

Figure 6A is a graph of a tank circuit response signal illustrating the change in threshold voltage values determined by the signal peak shape.

Figure 6B is a graph of a simulated family of curves for an initial (pre-radiation) threshold voltage value (Vth) and the corresponding dose found by following the curve/line associated with the initial value to the altered threshold value.

Figures 7A and **7B** are process control graphs which can be used to monitor the radiation process over a period of time according to the present invention.

Figures 8A and 8B are graphs that illustrate a simulated sensor response to various radiation dose levels according to the present invention.

Figure 9A is a graph of a frequency spectrum of the shunt path of a parallel resonant tank voltage illustrating the harmonics associated therewith (the fundamental is shown at 1kHz). The frequency spectrum (or a portion thereof) can be used to

determine the shift in threshold voltage upon exposure to radiation which can then be correlated to radiation dose according to one embodiment of the present invention.

Figure 9B is a simulated graph of the fundamental signal peak variation attributed to increasing radiation exposure levels (shown at 160kHz). As shown, the delta (difference) between the threshold voltage levels associated with the amplitude increases with increasing radiation.

Figure 9C is a graph of simulated responses of a harmonic of the frequency spectrum of a parallel resonant tank voltage, again showing that the delta (difference) between the pre-radiation value and irradiation exposed values, increases with increasing radiation exposure.

Figure 10 is a perspective view of a sealed container with a radiation sensor positioned thereon according to the present invention.

Figure 11A is a top schematic view of a radiation sensor according to one embodiment of the present invention.

Figure 11B is a side view of one embodiment of a multi-layer sensor according to the present invention.

Figure 11C is a top schematic view of a radiation label according to the present invention.

Figures 12A and **12B** are circuit diagrams of alternate embodiments of tank circuits suitable for use as a sensing element in one embodiment of the present invention.

Figure 13 is a graph of Hfe vs. total applied dose for a 2N2222A NPN transistor.

Figure 14 is a diagram of a dosimetry tag according to embodiments of the present invention.

Figure 15 is a schematic illustration of a method for determining and identifying parametric (pre-radiation) characterization of dosimeter tags according to embodiments of the present invention.

Figure 16 is a schematic illustration of a process flow at an irradiation facility according to embodiments of the present invention.

Figure 17 is a schematic illustration of a radiation sensor according to embodiments of the present invention.

Figures 18A-18C are graphs of operational waveforms of simulation results which may be used in assessing radiation based on a circuit such as that shown in **Figure 17** according to certain embodiments of the present invention. **Figure 18A** represents the power delivered by the primary circuit to the secondary (ID tag) circuit. **Figure 18B** is the waveform of the power oscillator voltage signal. **Figure 18C** is a waveform associated with the voltage across the capacitor C1.

Figure 19 is a diagram of a circuit having extended sensor range according to embodiments of the present invention.

Figure 20 is a diagram of alternate embodiments of circuitry according to embodiments of the present invention.

Figures 21A-12C are graphs of waveforms of simulation results over time for the circuit shown in **Figure 20**. **Figure 21A** is a graph of the primary power and the sensed signal over time. **Figure 21B** illustrates the primary voltage from the controlled oscillator (E19 in **Figure 20**) over time. **Figure 21C** illustrates the capacitive voltage (C19C in **Figure 20**) over time; the top curve representing an Hfe of 10, the middle curve representing an Hfe of 20, and the bottom curve an Hfe of 80.

Figure 22 is a circuit diagram of a sensor circuit employing a PNP transistor according to other embodiment of the present invention.

Figure 23 is a circuit diagram illustrating a sensor circuit comprising a diode according to embodiments of the present invention.

Figures 24A-24C are graphs of waveforms of a simulation using the circuit of **Figure 23**. **Figure 24A** illustrates the rectified average primary current in the circuit of L19A/C19A in **Figure 23** over time. **Figure 24B** illustrates the C19C voltage over time. **Figure 24C** illustrates the E19 voltage over time.

Figure 25 is a circuit diagram for measuring radiation according to still other embodiments of the present invention where the Q of the circuit corresponds to total dose.

Figure 26 is a graph illustrating the relationship between Q and Hfe based on the circuit shown in **Figure 25**.

Figure 27 is a circuit diagram of a full-bridge diode dosimeter according to embodiments of the present invention.

Figure 28 is a schematic illustration showing components associated with a dosimeter tag according to embodiments of the present invention.

Description of Embodiments of the Invention

The present invention will now be described more fully hereinafter with reference to the accompanying figures, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Like numbers refer to like elements throughout. In the figures, layers, regions, or components may be exaggerated for clarity.

Generally described, the present invention provides economical systems, computer products, and methods to estimate, determine, measure, and/or quantify radiation exposure by and/or the amount of radiation which is transmitted to an object (or a plurality of objects) *in situ* by detecting a change in a selected electronic parameter(s). The value of the change in the selected parameter may be wirelessly or telemetrically relayed to a remote or proximate reader/receiver. The reader can input the data associated with the parameter into a signal processor, controller or computer, which can calculate a corresponding radiation dose. The radiation dose measurement can be easily input (uploaded or downloaded automatically) into an electronic process control data record which can be searched and provide regulatory documentation associated with the food item and/or the production lot. In certain embodiments, the system is configured to measure the radiation dose on the object *in situ* by activating a passively operated electronic sensing circuit disposed proximate to the object or product via an inductively coupled telemetric or wireless reader and monitoring a selected electronic parameter associated with the electronic sensing circuit.

The systems of the present invention may be configured to operate without requiring labor-intensive efforts by operating personnel to measure the radiation dose as it is delivered to the irradiated product or object (such as foodstuffs). In certain embodiments, the system be configured to operate substantially automatically to quantify and record the radiation dose in an electronic database without requiring direct human manipulation of the irradiated product to determine an associated radiation dose. The system can be configured to operate in ambient and hot and cold

environments (*i.e.*, environments associated with the cooking temperatures of foods, or refrigerated or freezer temperatures used to process foods).

The methods and systems of the present invention are particularly suited for electronic pasteurization to measure radiation doses delivered to packaged, and preferably, sealed, food items undergoing radiation-based sterilization. As used herein, the term "electronic pasteurization" and/or "sterilize" means to irradiate to a level sufficient to meet or exceed minimum regulatory guidelines for identified undesirable microorganisms or food borne microbes.

The food items may be irradiated to provide an increased shelf life over non-electronic pasteurized counterparts while staying at or below the maximum irradiation level mandated by the appropriate regulatory agency. The food may be irradiated to produce a reduction in identified pathogens including one or more of *Salmonella*, *Listera*, *Tosoplasma*, *Campylobacter*, *Norwalk-like* viruses, and *E-coli* 0157:H7 over non-treated samples or foodstuffs as determined using conventional or standard techniques known in the art.

In one embodiment, "fresh" uncooked food items are electronically sterilized so as to destroy or reduce microorganisms sufficiently to provide an extended non-refrigerated shelf-life or refrigerated shelf-life (preferably providing a shelf-life which is at least one week, and preferably, 2 weeks-4weeks, or 4 weeks or more) over corresponding non-sterilized foods as determined using conventional or standard techniques known in the art.

Examples of food items suitable for radiation-based sterilization or "electronic pasteurization" include, but are not limited to, meats including frozen and/or unfrozen uncooked or cooked meats such as poultry, fish, beef and pork, and "fresh" fruits and vegetables, particularly those which are at increased risk of decay and a limited shelf life, including strawberries, blueberries, raspberries, peaches, grapes, tomatoes, zucchini, squash, lettuce, cabbage, broccoli, cauliflower, corn, green beans, egg plant, and the like. Other perishable food items (typically limited shelf-life products) such as baked goods, mushrooms, spices (such as gingerroot, and basil), and the like or candy may also be suitable for radiation-based sterilization. In addition, other food items suitable for such treatment includes pet foods, grains, wheat and corn flour. **Figure 1B** is a table of the list of foods approved for irradiation in the United States

along with the FDA recommended maximum doses. The list of foods and/or the radiation levels are subject to change over time, and may vary in different countries; as such, this list is not intended to be limiting to the present invention.

The system can be configured to measure a radiation dose for each product or with each package, or, alternatively, on one or more selected specimens or groups of products within a production lot or production run (one machine set-up and/or one shift), or at other desired processing intervals. If the measurement is selectively performed (as opposed to being performed on each item or product or on each packaged grouping), it is preferred that the specimen or product be selected so that it can provide a statistically relevant inspection data point(s) representative of other specimens in each production lot. **Figures 7A** and **7B** illustrate automated process control charts than can be generated to track exposure time and doses for a particular product or system over time. The system can be configured to generate an audible alert whenever the process range departs acceptable deviations to allow the process-input parameters to be adjusted.

Turning now to **Figure 1A**, a monitoring system **10** for a radiation-based sterilization process is shown. The system **10** is operably associated with a radiation source **20** and includes a radiation sensor **30** comprising a sensor circuit **31**. In operation, the radiation sensor **30** is positioned adjacent and/or in contact with an object **38** undergoing sterilization. Alternatively, the sensor **30** can be disposed on an external or internal portion of the associated packaging of the object **38** (either on the cover, backing, or container portion of the packaging) or at other locations proximate to the object(s) or containers thereof. **Figure 1A** also illustrates examples of foodstuff and medical tools (beef or hamburger patties (frozen or unfrozen or cooked or uncooked), apples, strawberries, poultry, and scissors (representing medical implements, devices, tools or other medical-use items)) which can be sterilized by radiation-based processes as described above (designated in this figure as element **39**).

As shown, the system **10** also includes a remote or wireless reader **40** which is positioned in the system **10** such that it can activate the sensor **30** via a telemetric link **33**. The system **10** also includes a controller **50** configured with a computer program or algorithm which is configured to process relayed data associated with the sensor **30**

and then determine or calculate the radiation dose based on the input of the relayed data.

Preferably, the reader **40** is positioned to reduce its exposure to radiation (such as appropriately shielded or disposed external of a batch or conveying line). As shown, the wireless telemetric link **33** and the reader **40** can be electrically coupled to the passive sensor **30** through an "H field" coupling as shown in **Figure 4**. If a reading is desired during active irradiation, a ceramic insulated coaxial wire can be used to provide the electrical connection (not shown), one end positioned proximate the sensor **30** in the radiation chamber and the other end operably associated with the external reader **40**.

Alternatively, a radiation reading can be obtained by obtaining information about the sensor both before and after active irradiation (not requiring wiring in the radiation chamber **20c** as shown in **Figure 4**. Of course, the "before reading" can be either provided by one or more of an *in situ* measurement obtained prior to irradiation and/or can be a test or manufacturer provided value, which can be electronically input into the control system, as will be discussed further below.

As shown in **Figure 2**, in operation, data associated with the sensor **30** is obtained telemetrically **(Block 100)**. The data associated with the sensor **30** (representative of one or more selected parameters thereof) can be obtained at various points during irradiation or at the conclusion of the irradiation. The data is then compared to predetermined values corresponding the value(s) to an associated radiation level(s) **(Block 110)**. The predetermined values can be one or more initial (pre-radiation) values taken *in situ* of the sensor, itself, or pre-radiation values associated with a particular production lot of the sensor being used. The initial (pre-radiation) values can be used to monitor shifts in parameters associated with the sensor or in the operation of the sensor (as will be discussed further below). The shifts in the monitored parameter(s) are, in turn, correlated to the amount of radiation to which the sensor, and hence, the object, is exposed. Alternatively, or additionally, the predetermined values can be experimentally or mathematically derived values associated with a predictable response of the sensor as it is exposed to various radiation levels (typically within a selected radiation range) for one or more selected

parameters. These derived values can be determined and included as a computer readable "look-up" chart loaded into the controller by the OEM.

The information can be provided in an initial set-up of the system, or for each type or each production lot of sensors. Again, the information can be configured in a downloadable electronic format, allowing the controller **50** to correlate the radiation exposure or dose based on the actual value(s) of the data correlated to the radiation dose needed to achieve such a value. Thus, the radiation dose of the object is identified based on the comparison with either initially measured values (*i.e.*, shift in the pre-radiation and post-radiation data) or with predictable response values for various radiation levels (**Block 120**). The predictable response values may be dependent on the type of radiation system employed. As shown, the measured or determined radiation dose can then optionally be automatically electronically entered into an electronic database associated with the process control record of the product or the production lot (**Block 130**).

Alternatively, as shown in **Figure 15**, each radiation sensor **30** can be individually evaluated for pre-irradiation parametric characterization in a mass production environment. In certain embodiments, a sensor housing, such as a two-piece lockable housing, can be introduced onto an assembly line. The housing **30H** can be configured from plastic or other elastomeric or inexpensive material to sandwich and/or mate together to hold circuit components which form the sensor **30**. The housing **30H** can be configured as a substantially rectangular shape so as to facilitate orientation/alignment for measurement or evaluation in an automated (machine based) manner. As shown, the housings **30H** can be serially fed onto a conveyor **300**. A continuous supply of components **31'** which are used as the active sensor circuits **31** can be fed to meet with the sensor housings **30H** to form the sensors **30** as they meet along the conveyor or assembly line. As shown, in certain embodiments the components **31'** can include a diode, bipolar transistor, MOSFET, or other suitable electronic or active component. For examples of sensor circuits **31** using diodes, see **Figures 23** and **27**, and for examples of sensor circuits using bipolar transistors, see **Figures 17**, **19**, **20**, **22**, and **25**.

As shown in **Figure 14**, leads **30w** of the circuit **31** or a selected component thereof can be configured so as to be accessible for external stimulation during the

parametric characterization. As shown, the leads **30w** extend out a length from the housing **30H**. Referring again to **Figure 15**, the sensors (which, in some embodiments may be descriptively termed "dosimeter tags") are then evaluated for parametric characterization **(301)** or pre-irradiation response values of one or more desired parameters of the sensor circuit **31**. This information can then be formatted into a bar code **(302)** which can be printed onto or attached as a label to the sensor **30**. The sensors **30** can then be packaged and shipped **(303)** to irradiation facilities. **Figure 14** illustrates the sensor **30** with the bar code **30BC**. As shown, the bar code is a label which is attached via an adhesive, VELCRO, double sided tape, or other desired attachment means. The attachment means operation **(304)** is shown in **Figure 15** as being applied to the sensor **30** prior to the label print out **(302)**.

In certain embodiments, an external attachment means **(304)** can be applied to the sensor **30** prior to the parameter characterization **(301)**. The attachment means can be used to attach the sensor **30** itself to the food items themselves or on packages or cartons of food items **38** undergoing radiation at the irradiation facility (*see, e.g.*, **Figure 15, block 305**). The bar code label **30BC** may have its own adhesive backing and can be attached to the sensor **30** after the parametric characterization (typically before shipping shown in **Figure 15** at **block 303**).

Figure 16 illustrates that the prepackaged radiation sensors or tags **30** can be applied to packages or cartons of food items **38** undergoing radiation. As shown, the bar code label **30BC** may be separated from the sensor **30** and positioned at a different (externally readable) location on the item **38** or on the container or package **138**, as desired. In other embodiments, the bar code label may remain with the sensor **30** (tag or package). The bar code label may include additional data, beyond just the parametric data, useful to the irradiation facility as described above.

After the product is irradiated by a radiation source **20** in the radiation chamber **20C**, it is evaluated by the electronic pasteurization or sterilization (dosimeter evaluation) monitoring system **10**. As shown, the bar code data with the parametric characterization information can be read and obtained via an optical scanner or reader **60** to scan the bar code **30BC** while the reader or primary circuit **40** activates the sensor **30** and the information is correlated in the controller **50** to determine dose. Alternatively, as shown by the broken line, the sensor **30** can be

removed from the package (either manually or in an automated manner) and a direct (electrical) contact reading can be used to obtain a dosimeter measurement. These operations may be performed sequentially or serially.

In certain embodiments, as shown in **Figure 1A**, the radiation dose is input as an electronic data record into a desired process or product history database used to hold process control records **60**. This database can be configured to receive, collect, and/or correlate important or desired information about the product (examples of such information are designated in the figure as **60r**), including the processing (packaging/irradiation) date, the measured or detected radiation dose, the production lot number, the incoming vendor or source of the food or other item, and the distributor or outlet destination.

In certain embodiments, the sensor **30** is configured with information **35** which can be electronically relayed or scanned and input into the process record. Optionally, as shown by dotted line in **Figure 1A**, the data or information provided by the sensor **30** is configured in a bar code label or computer readable format, which can be input into the database after it is read by an opto-electronic reader or scanner **60** or input device well known to those of skill in the art. As such, the sensor **30** can include one or more of sensor product identification, serial number, date of manufacture, and manufacturer or vendor, as well as an assigned production lot number or serial number for tracking the processed product itself, as well as the parametric characterization information, as desired, each potentially allowing for easier identification of products needed to be recalled or tracked for process control and/or inventory tracking of the product. In addition, or alternatively, the "tracking" device can be an RFID tag as is well known in the art. Preferably, for radiation-sensitive devices which are used to hold the production history or selected process (electronically accessible) information, the device is either shielded during radiation to maintain the integrity of the data or the device is accessed and read (and input into the system records) prior to irradiation as the radiation exposure may destroy the functionality of the device.

As is also shown in **Figure 1A**, the controller **50** can be configured to control the activation period or exposure time of the radiation source **20**. That is, the sensor **30**, the controller **50**, and the radiation source **20** can be configured to operate as a

control system having a feedback loop **75**. In operation, the sensor **30** transmits data responsive to inductive activation by a signal sent thereto from the remote wireless reader **40.** The data transmitted is analyzed to correlate it with the quantity of radiation received by the sensor (and hence the irradiated object/food) at that point in time. The controller **50** processes the received or transmitted data and determines the level of radiation or radiation dose for the product **38**. A computer readable look-up program or chart can be accessed identifying the process control limits for the appropriate radiation dose for this particular product (smaller and larger objects may have different preferred radiation levels). If the determined radiation dose is below the desired level, the radiation source continues in the operative mode to transmit radiation **20r** and irradiate the object **38**. These steps can be carried out at selective intervals, but are preferably performed to allow a substantially continual reading of the signal frequency.

Figure 3 illustrates the sequence of events for one embodiment of a method according to the present invention. The sensor **30** is positioned on or adjacent the object **38** undergoing sterilization. An initial or first pre-radiation reading of the sensor circuit **31** is obtained **(Block 200)**. The reading can be obtained after the sensor **30** is positioned on or adjacent the object **38**. Alternatively, the initial reading can be established remote from the radiation site (such as at a testing laboratory or OEM facility). The object **38** and sensor **30** are then irradiated **(Block 210)**. A second reading of the circuit is then telemetrically obtained **(Block 220)**. The first and second readings are compared **(Block 230)**. The radiation dose is then calculated based on the comparing step **(Block 240)**.

In certain embodiments, a plurality of readings can be obtained during active irradiation. These readings can be used to monitor radiation delivered and/or to allow an operator the ability to control the elapsed radiation period with dynamic information received during the actual delivery of the radiation. A metal antenna can be placed with the sample which can serve as the coil for the signal pick-up. Also, the monitoring system **10** can optionally be configured to compare one or more of the readings to a desired dose value correlated to a particular product **(Block 260)**. In addition, a plurality of sensors **30** can be positioned on a large package of foodstuffs (such as spread about a pallet or bulk package) to allow assessment of multiple

locations about the product (facilitating a more thorough evaluation for thicker, bulkier, or larger items). If the detected radiation dose is less than desired for the product undergoing radiation, the process can proceed (**Block 250**); however, if the radiation dose exceeds or meets the desired dose, the radiation source can be interrupted, preferably automatically, and the process ended. The "reading" of the circuit is based on one or more selected parameters that are altered in relation to the amount of radiation exposure, thereby allowing radiation dose to be quantified. As above, readings can be obtained at various points during irradiation or one or more readings can be obtained after the irradiation process has ended.

As shown in **Figure 4**, the electronic pasteurization or sterilization monitoring system **10** is operably associated with a conveyor-based **19** irradiation delivery system. As shown, the monitoring system **10** includes a first reader **40f** and a second reader **40s**, each providing a telemetric link **33** (shown as an "H-field" coupling). The first reader **40f** is positioned to take a signal reading before the radiation chamber **20c** and the second reader is positioned to take a signal reading after the radiation chamber **20c**. In operation, the two readings can be compared and a radiation exposure dose determined. As shown by the enclosed dotted line, in this embodiment, each reader **40** includes a resonant tank circuit **41** with an associated inductor and capacitor **41L**, **41C**, a tank driver **42**, and a receiver **43**. The readers **40** are each in communication with the controller **50** which includes the signal processing and control logic. The controller **50** can be operably associated with a remote or local CPU or other computer **50'**.

The system **10** can include a dynamic visual QC (quality control) feedback such as a red light/green light which can be activated and displayed, the green light indicating that the radiation dose is confirmed as in the desired range (not shown). Alternatively, or in addition thereto, the system **10** can be configured with an audio alert (not shown) which is generated when the radiation dose is determined to be outside a predefined range (which may vary for the type of object or food type undergoing irradiation). The audio alert may allow for timely adjustment of the process (slowing or speeding the conveyor speed to adjust the residence time, or otherwise adjust the process parameters) while potentially reducing the amount of discrepant product produced.

Turning now to the sensor **30** itself, the present invention employs an electronic circuit **31** which is influenced by irradiation. That is, the electronic circuit **31** is configured such that it predictably alters its behavior responsive to a particular radiation exposure range. The system **10** and/or the sensor **30** can be selectively configured to irradiate predefined items thereby allowing customization of the system or the system for each plant or processing facility. For example, for irradiation systems which process poultry or chicken, the system **10** and the sensor can be configured to detect doses corresponding to the FDA guidelines (the maximum is for chicken is presently set at 3kGy, see **Figure 1B**) about the 1-5kGy range (to quantify the doses which are above and below the maximum level).

Alternatively, the system **10** can be configured to operate across a variety of irradiation doses and/or with sensors **30** which also operate across a wide variety of applications and corresponding doses. For food, the sensor **30** is configured to operate predictably in a radiation range of from about 0.1-10 kGy, and more preferably, for meats, from about 1-5 or 1-7kGy. For spices, herbs, animal foods and the like the system is preferably configured to operate predictably up to at least about 31kGy (slightly above the FDA maximum dose range). For non-edible items such as medical devices, tools, and implements, the sensor **30**, is preferably configured to operate at increased radiation exposures, such as up to about 10-75kGy, and typically at about 20-50kGy. More preferably, the sensor **30** is configured to operate over a broad range of radiation doses to allow for use with multiple food products (*i.e.*, from 1-10kGy, 0.1-10 kGy, 0.5-5kGy, 2-4kGy, 1-5kGy, and the like).

In operation, when exposed to radiation, one or more electrical parameters associated with the circuit **31** will alter or change depending on the amount of radiation exposure the electronic circuit **31** receives. In certain embodiments, the electronic circuit **31** is configured such that it is passively activated and cost effective, even when used in a mass production environment, *i.e.*, low cost and disposable after a single use.

Examples of parameters suitable for correlating to radiation dose in the electronic circuit **31**, include, but are not limited to, threshold voltage (shift) in MOS devices, voltage or electrical current characteristics in certain circuits, operational variants caused by defect creations introduced by irradiation-based destruction of the

material layers in semiconductors, resonant frequency, frequency spectrum analysis of the signal of a circuit, conductivity of the dielectric material, the Q factor of the circuit (defined below), capacitance (or apparent capacitance) and/or resistance such as in the tank circuit, dielectric constant of the dielectric material in the tank circuit, the Hfe or β of a bipolar transistor, leakage current in a diode, the coupling factor "K" and the like, according to various embodiments of the present invention. In operation, the selected parameter will present a detectable and predictable, computatable or correlatable altered state or value from a "before" radiation value and to an "after" (or during) radiation value(s).

Figure 5A illustrates one embodiment of the electronic sensor circuit **31**. As shown, the electronic circuit **31** comprises a "tank" resonant circuit. In this embodiment, the tank circuit comprises an inductive element **31L,** a capacitive element **31C,** and a MOS device **31M**. The circuit **31** can also include a diode **31D**. As shown, the circuit **31** includes a shunt path **31s** which directs current away from the electrical path with the capacitor **31C** when the voltage is above the threshold voltage level of the MOS device **31M**. **Figure 5B** schematically illustrates this function. Thus, in this embodiment, a MOS or MOSFET device **31M** can be used to modify the properties of the tank LC tank circuit. The MOS or MOSFET can form or provide capacitance in a shunt circuit **31s** because the capacitance of the MOSFET is a function of the applied voltage. Upon exposure to radiation, the dosimeter circuit **31** is configured such that the relationship between capacitance and applied voltage is altered.

Generally stated, in operation, the MOSFET response in the shunt circuit **31s** operationally changes based on the amount of trapped charge introduced from the ionizing radiation source, which is created in the gate oxide of the device. That is, this trapped charge, can, within a desired radiation exposure range, alter the response of the circuit **31** to an applied voltage value. Thus, the response of the shunt circuit **31s** before and after exposure to radiation (to an applied voltage) within the desired radiation exposure or operational range is such that the MOSFET output or response changes, which can be detected correlated to determine the radiation dose associated with the change in response. Depending on the radiation exposure operational range of the sensor **30**, "rad hard" MOSFETS can be used to ensure that the damage

threshold is in the desired dose range. As MOSFETS are generally small and inexpensive, they can be economically integrated into a radiation sensor **30**.

As shown, in **Figure 5B**, an increase in V1 models the drop in MOSFET threshold voltage associated with radiation exposure to the sensor circuit. Thus, when the voltage shown as "V1" is applied to the circuit **31** (representing a level above the threshold voltage of the device **31M**), electrical current is directed away from the first leg of the path and into the shunt path **31s** (the shunt current). As the V1 voltage increases, more current is directed into the shunt path **31s**. The current directed into the shunt path **31s** acts to clip the shape of the response or reflected signal or waveform, which, in its purest form, is a sinusoidal wave, but as the shunt current increases, is a clipped waveform. **Figures 5C** and **5D** illustrate the waveform change. The system **10** can increase or decrease the applied voltage until the threshold voltage is substantially approached according to known sampling and statistical computation techniques. **Figures 5E** and **5F** illustrate that the MOSFET embodiment can be provided as either a P-channel (**Figure 5E**) or an N-channel (**Figure 5F**) type device, **31M, 31M'**, respectively.

Thus, in this embodiment, the tank circuit **31** is excited and the reader **40** "listens" to or monitors the reflected resonant signal. If the received signal is a high purity sine wave (a wave without substantial clipping of the top of the waveform), this means that the threshold voltage of the MOS device is above the peak voltage of the parallel resonant tank. If the resonant circuit signal is truncated or clipped, the voltage threshold, which is proportional to the magnetic field ("H-field") produced by the reader coil, can incrementally be decreased to determine the value.

Stated differently, during operation, an excitation pulse with a known voltage is transmitted to drive the circuit **31**. The circuit then "rings down" in a damped fashion according to a known time constant. The amplitude or signal waveform can be monitored to define the level at which there is no (or substantially no) current traveling through the shunt **31s**. This same measurement or monitoring can be performed on the exit side of the irradiation chamber **20c** as shown in **Figure 4**. The before threshold voltage can then be compared to the after radiation threshold voltage to determine the corresponding radiation dose (the dose level which produces this variation or shift). A correlation curve, equation, or look up table can be established

to provide the correlation of radiation dose to shift values (separate curves may be established for each production lot or for a plurality of dose ranges of interest).

Figure 6A graphically illustrates a simulated change in voltage threshold values (representing the values before and after radiation). Thus, before radiation, a threshold voltage of about 2.8v is indicated. "After" radiation the two waveforms shown thereunder illustrate the same waveform shape having a smaller amplitude signal corresponding to lower threshold voltage values (one at 0.5 volts below the first and the other at 1.0 volts below the first). Using a comparison of the change in voltage threshold values may provide improved reliability and consistency for dose determinations because most available dosimeters have a relatively large threshold voltage range (*i.e.*, -1.0v to +0.4v). Alternatively, a family of dose correlation (bias) curves or relationships can be established for various initial threshold values as shown for exemplary purposes in **Figure 6B**. Thus, for a sensor circuit **31** with a starting (pre-irradiation) voltage of 4 volts, one could (manually or electronically) compute the dose by matching the value of the post irradiation threshold voltage (or during irradiation) along the 4 volt curve or line to determine the appropriate dose on the bottom axis to quantify the corresponding exposure radiation dose.

Thus, monitoring when the clipped signal appears (or disappears), one can determine the value of the threshold voltage. As the MOS device **31M** has a threshold voltage which is either known based on statistical inspection of a related production batch (such as values provided for each wafer batch) before irradiation or is quantified proximate in time to and before irradiation, a pre-irradiation threshold value can be established.

Figures 8a and **8B** are plots of a simulated dosimeter or sensor circuit **31** response to various radiation dose levels. **Figure 8a** illustrates the decreasing amplitude (threshold voltage) corresponding to the monitored response of the sensor circuit **31** correlated to radiation dose (represented in kGy). **Figure 8B** illustrates the sensor circuit **31** voltage waveform for various irradiation levels (from 0-10kGy). As shown, the "O" or pre-irradiation level is the largest amplitude waveform (close to 3.8 volts), with increasing exposures generating smaller amplitude waveforms.

The MOS device is preferably a RADFET configured to operate predictably with sufficient sensitivity in a desired dose range (preferably a range which extends

above and below the maximum FDA value) for the particular food item or medical item undergoing evaluation. For example, for poultry a dose range of between about 1-4kGy. One MOS device which may be suitable for meat applications is the 300/50 device 4kÅ implanted gate oxide sold state dosimeter NMRC RADFET available from National Microelectronics Research Centre in Cork, Ireland.

It is expected that, by varying the density and/or percent material composition of the oxide/nitride layers, application or range specific MOS devices such as RADFETS can be produced which will provide the sensitivity, predictability or correlatable information in desired operative radiation ranges. For example, selecting the manner in which the oxide is grown, the addition of silicon nitride and the like are known ways to adjust the "rad-hardness" of the device (or the susceptibility of the device to radiation damage). Radiation can introduce a fixed charge that is trapped near the oxide/semiconductor interface, which causes a shift in the C-V characteristics of the MOS device (producing the threshold voltage shift discussed above). That is, semiconductors can be configured to exploit a number of interesting radiation effects to quantify radiation exposure. For example, the change in the trapped charge induced in the MOSFET structures. This can be a sensitive metric, which can be measured as an actual shift in "apparent" capacitance, or as described above, a shift in threshold voltage. At increased dose levels, conductivity can be affected (attributed to "defect" formation) which may be used for radiation quantification as well. Recombination times in the bulk can be shortened due to irradiation too. *See* Dienes et al., *Radiation Effects in Solids, Monographs in Physics and Astronomy*, Vol. II, Interscience Publishers, Inc., © 1957. The contents of which are hereby incorporated by reference as if recited in full herein.

In one embodiment, as shown in **Figures 9A-9C**, one or more frequencies in a frequency plot can be generated and compared (before and after or during radiation) for the tank circuit. In so doing, the analysis can be carried out in the time domain, where the waveform can be digitized and the waveform amplitude measured and determined or, in the frequency domain, where a distortion analysis of the waveform can be performed to measure the distortion and quantify the radiation which caused the distortion.

As is known to those of skill in the art, the sensor **30** voltage signal reflected back to the receiver or reader **40** can be Fourier transformed. In this embodiment, the present invention uses a waveform analysis to determine the change in threshold voltage. If a pure sine wave is detected, a 1V peak at 1.0kHz will be generated. However, if the shunt path **31s** is activated and the waveform of the sensor tank circuit altered, various harmonic peaks will also appear, as shown in **Figure 9A**. As shown, although a strong signal is shown at 1kHz, several harmonic peaks (much smaller in amplitude) to the right of the primary or fundamental peak, also appear. The present invention recognizes that the fundamental peak is associated with the **31L-31C** path of the tank circuit while the harmonics are associated with the shunt path **31s**. Therefore, the harmonic evaluation or a waveform distortion analysis can be computationally undertaken by the system **10** to determine the threshold voltage level corresponding to the change in amplitude of one or more of the fundamental or a harmonic waveform peak.

Figure 9B illustrates that the amplitude of the fundamental (shown at 160kHz) changes in response to radiation exposure and this information can be used to determine the shift in threshold voltage (similar to the discussion above). As shown, the delta (difference) between the threshold voltage levels associated with the amplitude increases with increasing radiation. Similarly, **Figure 9C** is a graph of simulated response of a harmonic of the frequency spectrum of a parallel resonant tank voltage, again showing that the delta (difference) between the pre-radiation value and irradiation exposed values, increases with increasing radiation exposure, which can be used to determine the radiation dose.

Thus, the ratio or difference of the threshold voltage corresponding to the amplitude of fundamental peaks (pre and post radiation) or a ratio or difference between one or more harmonic peaks (pre and post radiation) can be used to determine the radiation dose. In the frequency domain, the system, is performing a distortion analysis of the waveform to determine the radiation dose associated with the altered waveform. Alternatively, the ratio between the fundamental and a selected harmonic can be used to provide a before and after radiation value. Using ratios can reduce the amount of processing distortion introduced into the measurement. The

system **10** can be configured for signal processing within the range of about 100kHz-100MHz, and more preferably within about 100kHz-15MHz.

As shown in **Figure 10**, in certain embodiments, the sensor **30** presents a substantially planar flat profile when viewed from the side. As such, the sensor **30** and/or sensor circuit **31** preferably comprises a flat form conductive coil **31F**, preferably formed of a metallic material such as copper, mylar, or the like defines or forms part of the tank circuit inductor **31L** so as to provide the inductive component and to act as the antenna for the sensor **30**. The conductive coil **31F** can be etched or inked or magnet wire wound to provide a desired inductance, attached to onto an underlying thin substrate or flex circuit material. The MOS device **31M** (such as the RADFET device) can be secured to and electrically engaged with the flat form coil **31F** along with the tank capacitor **31C** to provide a tank circuit **31**. As described above, in operation, the circuit **31** can be passively activated/operated (without requiring a power source) and resonated by the reader **40** or primary circuit **40C** through an inductive coupling **33**.

Figure 10 also illustrates that the sensor **30** can be applied to a packaged (which may be tamper resistant-sealed) product such that there is no need to disrupt the sealed package after irradiation to reduce the likelihood that pathogens may be introduced after irradiation is complete. The sealed package does not need to be airtight but is preferably configured to allow the product held therein to be isolated from undesirable exposures prior to purchase and/or the end use point. As shown in **Figure 10**, the sealed or enclosed product includes a base container **138** (such as a foam, cardboard, basket, pallet, or other base which can hold the weight of the product(s) therein) with a sealant **238** overlay. The sensor **30** is shown on the outside of packaged product but can be placed on the backside or the inside of the package.

In one embodiment, as illustrated by **Figure 11A**, the underside of the sensor **30u** can include a releasable adhesive to allow the sensor **30** (when attached to the outside of a product, food item, package, or sealant) to be secured to the desired object during processing and then easily removed without harming or tearing the underlying package, product, food item (skin or surface) or sealant material.

Further, as shown in **Figure 11C**, the sensor **30'** can be configured such that upon removal of the sensor circuit **31**, any regulatory required marking, such as the

approved visual indicia or logo **531** indicating the food has been electronically pasteurized can be displayed. Preferably, in this embodiment, the sensor **30'** includes a first layer **330** which holds the sensor circuit **31**, and an underlying second "label" layer **530**. The sensor **30'** also includes a releasable attachment (such as a double-sided tape or adhesive or other detachable bond) **430** therebetween. The bottom or underlying surface of the label layer **530** also preferably includes an attachment means **533** such as an adhesive or tape (single or double sided (preferably polymer tape)) applied thereto or formed thereon which has an increased bond strength so that, in operation, upon removal of the circuit layer **330**, the label layer **530** remains in position on the object. Thus, the circuit layer **330** preferably has a peel strength which is less than the bond strength of the attachment means **533** of label layer **530** to the underlying object.

In operation, the sensor **30'** is positioned on and attached to a desired object such that the circuit **31** is facing away from the object. After irradiation, the sensor layer **330** is detached from the sensor **30'** exposing the label layer **530** which then presents the radiation identifier or logo **531** such that is viewable by consumers or potential or actual purchasers.

Figure 28 illustrates another embodiment of sensor **30** or dosimetry tag **30t**. As shown, the sensor circuit **31** is held on a thin substrate **28C** and is associated with a bar code label **30BC** with parametric data encoded thereon. The sensor **30** can include a printed circuit board **30PCB**, a winding of magnet or conductive wire **31F'**, and leads **30W** which connect the two.

Other tank circuit configurations can also be employed as noted above. The tank circuit is configured such that, in operation, the resonant frequency of the electronic (tank) circuit can change in a detectable manner and/or the sharpness (*i.e.*, represented by the "Q" factor which corresponds to the resonant frequency, the inductance, and the resistance of the circuit) of the tank circuit can change in a detectable manner responsive to the level of radiation. Alternatively, the radiation dose can be calculated based on a detected change in the value of the capacitance of the capacitive element **31C** of the circuit (pre and post radiation). That is, recognizing that the resonant frequency (ω) of the tank circuit can be mathematically expressed as $\omega=1/(LC)^{1/2}$ and the capacitance can be expressed as $C=(A\varepsilon)/d$, where "ε" is the

dielectric constant of the insulator material, "A" is the area of the capacitor, and "d" is the thickness of the dielectric' (the capacitance is a function of dielectric permitivity, the plate area, and distance between the plates). Similarly, the Q factor can be expressed as $Q=\omega L/R$, where "R" is the resistance in the tank circuit, and "L" is the inductance value of the inductive element **31L**, one or more of these parameters can be used as a basis for determining radiation dose.

For example, as shown in **Figures 12A** and **12B**, the electronic circuit **31** can be configured with the capacitor **31L** formed from a center dielectric insulator material **90**, selected based on its ability to predictably alter the capacitance value in response to radiation. The capacitor **31L** includes two opposing outer layers **91, 92** formed from thin flat metallized layers or metal or foil plates positioned to sandwich the center dielectric material **90**. **Figure 12B** illustrates the use of a resistor **31R** which may be provided in a number of ways as is well known to those of skill in the art, such as by the substrate material holding the elements **31L, 31C,** or as a separate discrete component. As described above, the inductive element **31L** can be formed as a flat conductive coil shaped to form the inductive element as is well known to those of skill in the art. In this embodiment, the center dielectric material **90** is selected based on its ability to alter its behavior in a predictable manner when exposed to radiation at sterilization exposure levels in the desired range(s). The inductive element **31L** is preferably configured such that it is left substantially unchanged from its non-irradiated state even after radiation exposure.

The insulator **90** may be chosen from a plastic or polymer based material, recognizing that certain plastics become cross-lined during irradiation, due, at least partly, to the formation of free radicals as a byproduct of ionizing radiation. This, in turn, can cause a change in the elastic property of the material. Taking a reading of the capacitance before and after radiation may provide a dose-correlatable value. Conductive polymers may also be employed because the source of conductivity is typically in a long-chain molecule and ionizing radiation is likely to cause cross linking that may interfere with the conduction process. Alternatively, the insulator material can be configured to comprise dielectric crystals or ferroelectric materials (such as $LiNbO_3$) which have a net polarization at room temperature. Radiation may induce detectable point defects in the material. Indeed, the dielectric constant of some

crystals (perhaps even LiF, a common TLD material) may change the dielectric capacitance in a detectable manner. The change could then be assessed to determine radiation dose.

In one embodiment, using a pre-selected insulator material to form the insulator or dielectric material of the capacitive element **31C** such that it can change the capacitance of the circuit (based on exposure to radiation), and, thus, result in an altered resonant frequency of the circuit **31**. The altered resonant frequency can be correlated to the amount of radiation received, thus providing an inexpensive way to quantify the radiation dose.

Alternatively, or additionally, the material of the insulator or dielectric **90** can be selected such that there is a change in conductivity of the material based on exposure to radiation. The resultant change in leakage current through the material may then alter the Q factor of the electronic (tank) circuit **31**. In another embodiment, the dielectric material **90** can be selected such that it comprises a conductive or weakly conductive polymer. Changes in the conductivity resulting from irradiation can also alter (typically decrease the conductivity) which could be measured as a change in the Q factor. The altered Q factor can then be correlated to radiation level to calculate the radiation exposure dose.

Other ways to induce detectable operative changes in the sensor circuit **31**, include the use of PN junction devices. The creation of radiation-based defects within the bulk of the silicon can alter recombination lifetimes in the depletion region of a diode. This change can be assessed, for example, by measuring the increase in reverse-bias leakage current of the diode. Still another way to induce detectable operative changes includes the use of radiographic or colormetric sensors. For example, the system can include an LED of a particular wavelength and a photodiode detector configured to operably engage therewith. The LED can be used to "look" at the color of a radiochromatic tag, similar to the tags conventionally used (as discussed in the background above). A photodiode detector can then produce a current proportional to the light from the LED directed into or passing through the radiochromatic material of the tag (not shown).

In other embodiments, another way to induce detectable operative changes in the sensor circuit **31** is to use a bipolar transistor. **Figure 13** illustrates a plot of Hfe

versus total applied (radiation) dose for a bipolar transistor; namely, a 2N2222A NPN transistor. As shown, the Hfe versus dosage of an exemplary NPN transistor is illustrated. This data can be obtained from a NASA radnet site (www.radnet.jpl.nasa.gov/TID). The data was fitted to Equation (1).

$$\text{Hfe} = 145.15*(1+\text{kGrey})^{-0.8057} \qquad \text{Equation (1)}$$

As shown, the Hfe of the transistor varies relatively substantially over the range of 0.01kGy to 50kGy. This variation can be detected using either direct contact or telemetric methods to establish total dose. As for other embodiments, in this dosimeter embodiment, the transistor can be characterized prior to irradiation and the characterization data can be stored in a computer database and/or printed on a bar-code label associated with the sensor **30**. In certain embodiments, which may be particularly suitable for direct contact detection or measurement methods (as opposed to wireless detection), the value of the pre-irradiation signal parameter (Hfe) can be used to normalize a desired curvefit equation. For example, if the transistor has an initial Hfe of 145 at a given Ic of 0.1mA and the Hfe of the post-irradiated transistor is measured at 20, then the dosage can be calculated using Equation (2).

$$\left(\frac{Hfe\,measured}{Hfe\,initial}\right)^{-\left(\frac{1}{0.8057}\right)} - 1 = dose \qquad \text{Equation (2)}$$

For an Hfe measured (post irradiation) of 20 and a pre-irradiation or initial Hfe of 145, this results in a computed radiation dose of 10.69kGy. This value is consistent with the curvefit and tabular data. As is well known to those of skill in the art, mathematical corrections may be made to the calculated result to adjust for gains at various temperatures and other desired variables.

Other transistors with Hfe degradation characteristics may be evaluated and a curvefit equation defined for that component. For example, a PNP transistor, such as a 2N2907A, has a similar Hfe degradation with exposure to radiation from sources such as Cobalt-60. The mechanisms for the Hfe degradation are known. *See e.g.*, Messenger et al., *The Effects of Radiation on Electronic Systems*, (Van Nostrand

Reinhold, 1992) and Ma et al., in *Ionizing Radiation Effects in MOS Devices and Circuits*, (Wiley, 1989).

In any event, the post-irradiation gain for the transistors may be detected or evaluated in a number of wireless or telemetric (non-contact) methods as well as via direct electrical contact according to embodiments of the present invention. In certain embodiments, the Hfe of the transistor can be inferred from a time, voltage, spectral content, or "Q" measurement and a radiation dose calculated (either directly or indirectly) from a mathematical model or pre-determined relationship of Hfe to dose.

Figure 17 illustrates a sensor circuit **31** with a BJT (Bipolar Junction Transistor), which may be an NPN transistor, configured to act as the dosimeter. In other embodiments, as will be discussed below, a sensor circuit **31** similar to that shown in **Figure 17** scan be configured so that a diode can be used to allow the dose to be determined. In operation, an RF means of determining a parameter shift in the transistor may be used to determined dose.

As shown in **Figure 17**, the sensor circuit **31** can include an inductor **131L2** (L2), a rectifying diode **131D** (D1), a capacitor **131C** (C1), a zener diode **131Z**, and a transistor **131Q** (Q1) shown with biasing resistors (R2 and R5). As noted above, the calibration (pre-irradiation or characterization) data can be used to correlate the post-radiation Hfe of the test transistor **131Q**. From the Hfe data, a statistical correlation and/or curve-fitting program can be used to determine the radiation dose delivered to the sensor **30** (and the object undergoing treatment). In certain embodiments, as shown in **Figure 17**, the primary side of the circuit **131P** (which may also form a portion of a wireless reader **40**) includes a controlled oscillator **131O** which, as also shown in **Figure 17**, includes components V1, V2, and E1. The primary circuit **131P** can also include current monitoring and conditioning circuitry (shown as components R3, E2, R6, D2, C3, and R7) as well as a coupling inductor **131L1**. The inductors (L1 and l2) may be either printed "wiring" or wire coiled or wound to a desired form. In operation, the capacitor **131C** on the secondary side of the circuit **131S** can be charged until the zener diode **131Z** voltage is reached. The power of the primary side **131P** can be monitored to determine when the capacitor is charged to the zener voltage. The oscillator **131O** can be turned off, and the secondary-side capacitor **131C** discharged through **131Q** (Q1). The rate at which **131C** (C1) is discharged is a

function of Hfe of **131Q** (Q1). At a time, t1, later, the oscillator **131O** can be re-powered, reactivated, or reapplied and the primary-side power **131P** can be monitored to determine when the secondary-side **131S** capacitor **131C** begins to recharge. From this information/data, the change in voltage on the capacitor can be determined and related to establish the Hfe of the transistor **131Q**. The Hfe values (before and after radiation) can be compared to determine the radiation dose. This dose can be recorded along with the serial number of the radiation sensor **30** as well as the food container as noted above.

Figures 18A-18C illustrate operational waveform graphs of simulation results for the circuit shown in **Figure 17**. The waveform shown in **Figure 18A** illustrates the power delivered by the primary circuit **131P** to the secondary circuit **131S**. This data may be obtained by integrating the voltage and current delivered to the primary side inductor and subtracting the primary-side idle power loss. The waveform shown in **Figure 18B** illustrates the power oscillator **131O** voltage signal. The waveform shown in **Figure 18C** is the voltage across **131C (Figure 17**, C1). In the example shown, the power oscillator **131O (Figure 17)** turns "on" at time t=0 to initially charge capacitor **131C (Figure 17**, C1) until time =5μs. The primary side can then detect when the capacitor **131C (Figure 17**, C1) is fully charged to the zener voltage **131Z** by evaluating the rate at which power is being delivered to the circuit. As shown, from time t=5μs to t=10μs, the power oscillator **131O** is "off" and the capacitor **131C (Figure 17)**, discharges. As is also shown, at time t=10μs, the power oscillator **131O (Figure 17)** is ramped back up and the voltage power is monitored. When the power oscillator **131O (Figure 17)** reaches the voltage where power is being drawn again to charge the capacitor **C1** (which can be determined from the primary detection circuitry in the primary circuit), the time from the beginning the of the power ramp voltage can be recorded/determined (t=10μs). Thus, the rate of power draw from the primary circuit **131P** to the secondary circuit **131S** can be monitored.

In certain embodiment, in operation when the primary circuit **131P** operates without a sensor **30** or tag with the secondary circuit **131S** within range, the energy drawn from the primary circuit **131P** is associated with the losses to oscillate the tank. This energy loss can be measured and stored (such as in a controller or signal

processor). When a sensor **30** with the secondary circuit **131S** is in the range of the detector, and hence the primary circuit **131P** (which may be identified by the barcode scanner), the energy drawn from the primary circuit **131P** can be represented as equal to the sum of the energy in: (a) the primary tank, (b) the secondary tank, (c) the energy to charge **131C** (C1) and (d) some "constant" losses associated with the zener and/or transistor circuits. The energy to charge **131C** (C1) may be determined by monitoring the energy delivered from the primary circuit **131P**. Because the value of **131C** (C1) and the zener **131Z** voltage are known (such as from the parametric characterization), the voltage discharge across **131C** (C1) can be calculated based on when the primary circuit **131P** begins to recharge the capacitor **131C**. The amount of voltage that the capacitor has discharged and the time can be used to correlate the Hfe of the transistor **131Q**.

The time where the capacitor **131C** (C1) has again reached the zener voltage **131Z** can also be determined. These two measurements can be used to determine the voltage discharge on the capacitor **131C** (C1) and this data related to the Hfe of the transistor **131Q**. The primary circuit **131P** can include primary detection circuitry (not shown) such as amplifiers, integrators, multipliers, and the like which can be used to monitor the energy transfer as is known to those of skill in the art. It is also noted that in certain embodiments, the E1 **(Figure 17)** voltage in the primary side of the circuit **131P (Figure 17)** may be adjusted to linearize the relationship between time/voltage measurements and the dosage relationship. The adjustments may be in time, amplitude, and/or frequency.

In certain embodiments, the following mathematical relationships and equations can be used to determine dose.

$$Vc_1(t_1) = \int_{to}^{t_1} -(i(t)dt)/C + V_{co} \qquad \text{Equation (3)}$$

Stated differently,

$$\Delta V_c = \int_{to}^{t_1} -(i(t)dt)/C \qquad \text{Equation (4)}$$

where ΔVc is known (it is measured at the time when power is drawn from the primary circuit **131P** until the capacitor reaches the zener voltage), in the example shown in **Figure 18**, the initial time is at about ($t=15\mu s$). The second time measurement is when the zener voltage is reached on the secondary side, at this time, the slope will change (such as at t=23-25 seconds). "C" is the capacitance of C1 and is a scaling constant and (i) is the current associated with the transistor. In addition, Vc_0 is known, it is the zener diode voltage. By measuring the voltage change over time indirectly, it is possible to determine i(t) and, thus, radiation dose due to Hfe degradation.

$$i(t)=i_c+i_b=hfe(dose)*ib+ib=ib(1+hfe(dose)) \qquad \text{Equation (5)}$$

where ic, ib are a function of dose.

In other embodiments, the Hfe value can be determined in other ways. For example, the "extra" energy delivered from the primary side **131P** to the secondary side **131S** during the recharge cycle can be measured to deduce the voltage change on the capacitor using the relationship represented as ($E=1/2CV^2$). That is, "E" attributed to the extra energy from the primary circuit **131P** is known (identify this value as E delivered), C1 is known and the Efinal is known because it is based on a known zener final voltage, and Eintial can be calculated. Thus Eintial can be calculated from Equation (6). V initial can them be calculated based on ($E=1/2CV^2$). Vinitial can be used to calculate the Hfe of the transistor.

$$E\ initial = E\ final - E\ delivered \qquad \text{Equation (6)}$$

Turning now to **Figure 19**, another embodiment of a sensor circuit **31** (similar to that shown in **Figure 17**) is shown. In this embodiment, the primary circuit **131P** includes the oscillator **131O**, a primary capacitor **131Cp** and an inductor **131L1**. The primary circuit **131P** can also include sensing circuitry to detect when the capacitor **131C** (C19C) has been charged to the zener voltage corresponding to the zener diode **131Z** (D19B). The secondary circuit **131S** includes a capacitor **131Cs** and the inductor **131L2** and may also include a diode **131D** which can rectify the signal from

131L2 (L19B) and charge capacitor **131C** (C19C). The secondary circuit can also include a biasing resistor **131R** which can adjust the bias on the dose sensitive transistor **131Q** (Q19A). The primary capacitor and inductor **131Cp, 131L1**, respectively, can be tuned to a resonant frequency similar to that of the secondary circuit capacitor and inductor, **131L2, 131Cs** to extend the range when the primary and secondary circuits may be coupled/operated but otherwise operates similar to the operation of **Figure 17** described above.

Figure 20 illustrates another embodiment along the lines of the circuit shown in **Figure 17**. In this embodiment, the circuit **31** includes circuitry means **231** to disable the flow of current in the transistor **131Q** (Q19A) while the signal is present across **131L2** (L19B). That is, the circuitry means **231** can disable the operation of the NPN transistor while the power oscillator is operating. As shown the circuitry means **231** includes components **D20A, D20B**, **C20A**, and **R20A**. This configuration may improve the measurement of the charging characteristics of the circuit because **131C** is charged by removing or inhibiting the influence of the transistor **131Q** circuitry.

Figures 21A-C illustrate simulated operational waveforms for the circuit shown in **Figure 20**. **Figure 21A** illustrates the primary power (sensed or detected) signal over time. **Figure 21B** illustrates the primary voltage from the controlled oscillator **131O** (E19). **Figure 21C** illustrates the **131C** (C19C) voltage. Note that the charging ramp is not influenced by Hfe. **Figure 21C** also illustrates three lines, one for each of three different Hfe values (the three lines appear in the graph after about 10ms).

Figure 22 is an illustration of yet another embodiment of a circuit **31**. As shown, the circuit **31** is similar to that of **Figure 17** but, rather than a NPN transistor, it includes a PNP transistor **131Q'** (Q22) and an associated bias resistor **131R'** (R22A).

Figure 23 illustrates yet another embodiment of the sensor circuit **31**. As shown, instead of a transistor, the circuit uses a diode **231D**. In this embodiment, the discharge of the capacitor **131C** is generated via the leakage current of **231D** (D23A). The leakage current can be a function of dosage that can be estimated by determining the change in voltage of **131C,** over time, as shown in **Figures 24A-C**. **Figure 24A**

illustrates the simulated rectified average primary current in the primary side of the circuit **131P** about the inductor/capacitor **131L1**, **131Cp**, respectively (the L19A/C19A circuit), over time. **Figure 24B** illustrates the voltage at the capacitor **131C** (C19C), and **Figure 24C** illustrates the voltage at the oscillator **131O** (E19).

Figure 25 illustrates an additional embodiment of the sensor circuit **31**. In this embodiment, the Q of the primary tank circuit **131Cp** (C19A), **131L1** (L19A) is measured and varies with the Hfe (and thus, total dose) applied to **131Q** (Q19A). This circuit can be reconfigured to operate with a PNP transistor similar to that shown in **Figure 22**. **Figure 26** is a graph showing the relationship between Q and Hfe in the circuit of **Figure 25**. The Hfe may be determined and correlated to dose as described above (such as for the embodiment shown in **Figures 13-18**).

Figure 27 shows yet another embodiment of a circuit **31** according to the present invention. As shown, a full-bridge **231Br** can be used to form the dosimeter **30**. That is, **131D** (D19A) is replaced with a full bridge comprising **D27A, D27B, D27C**, and **D27D**. The full bridge configuration may increase signal strength. The full bridge configuration may be added to other circuit embodiments described herein.

The present invention provides a cost effective way to monitor radiation doses in irradiated foods by configuring the sensor circuit to change in response to exposure to radiation. The dosimeters may be suitable for mass-production environments and can include means to wirelessly or telemetrically relay detected parameter values associated with changes due to radiation exposure to a computer program adapted to calculate and provide the associated radiation dose without requiring labor intensive efforts on the part of an inspector or operator. The radiation dose can also be read during exposure to provide an input into a feedback control used in a radiation control system to facilitate proper radiation exposure.

Irradiation may be carried out by suitable modalities as is known to those of skill in the art. For example, by directing radiation to the object undergoing the procedure in an amount sufficient to achieve sterilization using a radioactive source or element such as, but not limited to, Cobalt-60, Cesium-137, electron beams produced by a linear accelerator, and the like. The irradiation process can be carried out by a stationary system or by a portable system where appropriate. The present invention

provides an economic, single use disposable sensor that can monitor the radiation dose to help indicate that pathogens are destroyed effectively.

As will be appreciated by one of skill in the art, the present invention may be embodied as an apparatus or system, a method, a data or signal processing system, or a computer program product. Accordingly, embodiments of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment, or an embodiment combining software and hardware aspects. Furthermore, certain embodiments of the present invention may take the form of a computer program product on a computer-usable storage medium having computer-usable program code means embodied in the medium. Any suitable computer readable medium may be utilized including hard disks, CD-ROMs, optical storage devices, or magnetic storage devices.

The computer-usable or computer-readable medium may be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium. More specific examples (a nonexhaustive list) of the computer-readable medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, and a portable compact disc read-only memory (CD-ROM). Note that the computer-usable or computer-readable medium could even be paper or another suitable medium upon which the program is printed, as the program can be electronically captured, via, for instance, optical scanning of the paper or other medium, then compiled, interpreted or otherwise processed in a suitable manner if necessary, and then stored in a computer memory.

Computer program code for carrying out operations of the present invention may be written in an object oriented programming language such as Java®, Smalltalk or C++. However, the computer program code for carrying out operations of the present invention may also be written in conventional procedural programming languages, such as the "C" programming language or even assembly language. The program code may execute entirely on the user's (monitoring site) computer, partly on the user's computer as a stand-alone software package, partly on the user's computer

and partly on a remote computer or entirely on the remote computer. In the latter scenario, the remote computer may be connected to the user's computer through wireless means and/or via a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

The flowcharts and block diagrams of certain of the figures herein illustrate the architecture, functionality, and operation of possible implementations of radiation dosimeters and associated systems according to the present invention. In this regard, each block in the flow charts or block diagrams represents a module, segment, operation, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that in some alternative implementations, the functions noted in the blocks may occur out of the order noted in the figures. For example, two blocks shown in succession may in fact be executed substantially concurrently or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. In the claims, means-plus-function clauses, where used, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.